Biomechanical Evaluation of Align Footwear Insoles
Brief Report[1]

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This report summarizes a study of Align Footwear's thermoformed insoles. The purpose of the study was to evaluate the insoles' effects on the alignment of the lower leg and foot and plantar loads during treadmill walking. In particular, we sought to test the validity of Align's performance claims:

(1) "A more neutral alignment of the foot"

(2) "Enhanced pronation control."

(3) "Improved cushioning "

We examined these claims by performing some mechanical tests and measurements of the insoles and by means of biomechanical testing. Loads on the foot and the motion of the foot, shoe and lower leg were compared during quiet standing and treadmill walking in 20 subjects. A stock EVA insole of the type commonly supplied with athletic shoes was used as a baseline comparison for reference.

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[1] A more detailed report is available on request. This includes more technical information regarding methodology, analytical methods, results, stand statistical analyses.

Summary of Outcomes

The outcomes of this study were consistent with Align's claims.

- In relaxed stance, the feet and lower legs of subjects wearing the Align insoles were more closely aligned to the reference subtalar neutral position than in the stock EVA insoles.
- Pronation and tibial rotation measures recorded during treadmill walking were reduced by ~2 - 3°
- Cushioning scores on mechanical impact tests and *in-vivo* measurements of in-shoe pressure distribution showed effects on peak impact shock, peak pressure and peak pressure rate measures that were consistent with "more cushioning".

More specifically[2]:

- Relative alignment of the tibia, heel and arch did not differ significantly between subjects standing barefoot and in shoes with conventional (EVA) insoles. With the Align insoles, however, alignment in relaxed stance was significantly closer to the palpated "neutral" orientation, by 32% on average. Internal tibial rotation and foot pronation were reduced (i.e. "more neutral") by 2.7° (40%) and 2.4° (27%) respectively.
- During treadmill walking, peak pronation of the rearfoot and arch were significantly reduced, by 3.1° (23%) and 1.7° (11%) respectively. Ranges of motion were reduced by 2.7° (11%) and 2.4 (15%) respectively. Internal tibial rotation was reduced by an average of 9.2° (20%).
- On average peak pressure under the heel was reduced by 10% and peak pressure rate ("impact") by 12%. There was no statistically significant difference in peak forefoot loads.
- In addition, we found the Align insoles to be lighter in weight than typical after-market insoles (1.6 ounces vs 1.8—3.6 ounces) and had only negligible effects on the forefoot flexibility of the test shoe.

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[2] Reported differences are statistically significant at the $p<0.05$ level.

Disclosure

BioMechanica, LLC is a privately owned, independent company that provides research, testing and other technical services to the sporting goods, military and medical industries.

The study described in this report was performed as “work for hire” subject to our usual terms of business. We were compensated at a predetermined, fixed rate.

Neither BioMechanica LLC nor its employees have any financial interest, direct or indirect, in Align Footwear LLC and its products.

BioMechanica LLC and its employees do not endorse products or services and do not allow their clients to use their names, images or work product in any context that suggests endorsement or approval of a product or service.

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Dynamic Effects of Insoles

See Appendix 1

Loads on the foot and the motion of the foot, shoe and lower leg were measured during quiet standing and treadmill walking in 20 subjects. In-shoe pressure distribution was measured using F-Scan pressure sensors. Lower extremity motion was recorded in three dimensions using a Natural Point motion capture system with 12 cameras running at 100 frames per second. For comparison, a conventional EVA insole was used as a control condition

In-Shoe Loads

Peak Pressure

Figure 1 shows an example of mean peak pressure distributions produced by the two insole conditions. Pressure distribution of primarily determined by the anatomy of the foot, and peak loads typically occur under the bony prominences of the heel, metatarsal heads big toe; sometimes under lesser toes.

Both the “hardness” and the curvature of the interface between the foot and the shoe can affect the distribution of loads. “Softer” surfaces and more conforming geometry spread load over a larger area and reduce peak pressures[3].

In this study, across subjects, the Align insole reduced peak pressure in the heel significantly, by 10%, on average.

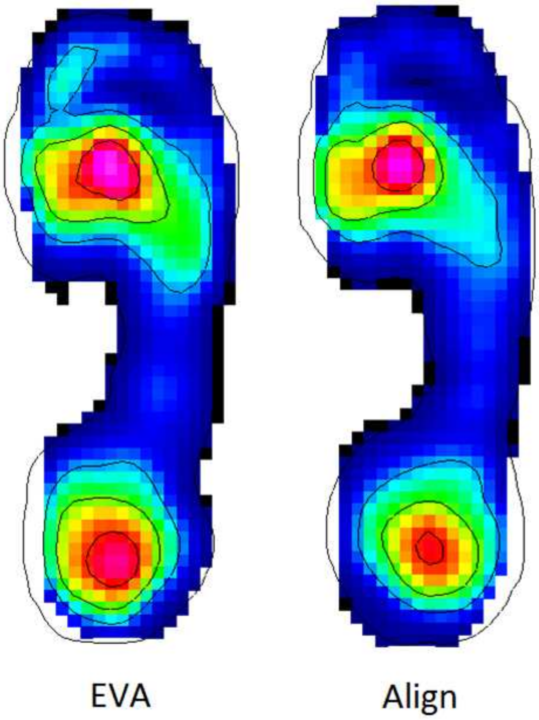

Figure 1: Mean peak pressure distribution during treadmill walking

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[3] Mientjes, M. & Shorten, M.R. (2011) *Contoured cushioning: effects of surface compressibility and curvature on heel pressure distribution.* Footwear Science 3(1):23:32.

Peak Pressure Rate

Figure 2 shows an example of mean peak pressure *rate* distributions produced by the two insole conditions. High rates of loading are associated with "impact" so during walking they are usually observed only in the heel region.

More compliant ("cushioned") surfaces underfoot tend to reduce loading rates.

In this study, across subjects, the Align insole reduced peak pressure rates in the heel significantly, by 12%, on average.

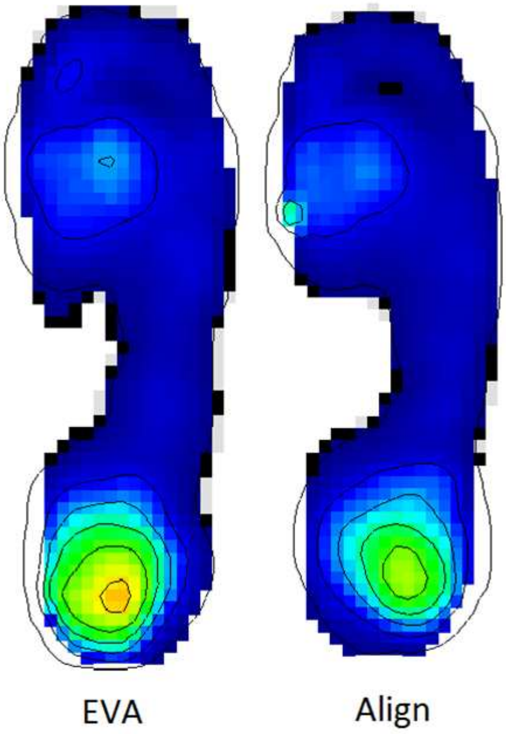


Figure 2: Mean peak pressure rate distribution during treadmill walking

Benefits of Load Reduction

"Cushioning" in footwear has three functions:

1. *Reduction of local peak pressure (stress) on the plantar surface of the foot.*
   Excessive repetitive stresses are implicated in various pathologies from minor discomfort and bruising to stress fractures
2. *Reduction of loading rate.*
   Higher loading rates at the plantar surface are indicative of "impact". Whereas the effects of cushioning on peak pressures are generally limited to the foot itself, variations in impact loading are transmitted through the musculo-skeletal system. The repetitive stresses produced during walking and running can have cumulative effects, resulting in "overuse" injuries. Since bone and soft tissues are more susceptible to loads applied at high frequencies, lower loading rates are believed to be advantageous.
3. *Enhancement of the perception of comfort.*
   "Comfort" is a psychological outcome, not a physical property of an insole or cushioning system. Cushioning systems that reduce pressure and impact stresses tend to be perceived as "more comfortable". However, in footwear, load-related comfort perception may be confounded with other factors including fit, flexibility and ventilation.

Lower Extremity Alignment and Motion

Alignment

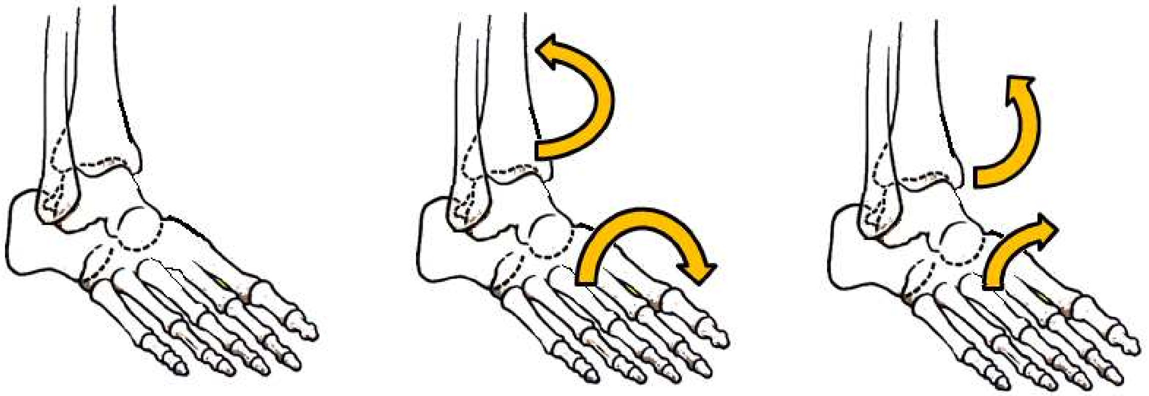
Measurements made during relaxed stance, in the neutral position, were use as the baseline for foot and leg alignment measures.

In all subjects and trials, the foot is more pronated and the tibia more internally rotated than in the “neutral” position

- Relative alignment of the tibia, heel and arch did not differ significantly between subjects standing barefoot and in shoes with conventional (EVA) insoles. With the Align insoles, however, alignment in relaxed stance was significantly closer to the palpated “neutral” orientation, by 32% on average. Internal tibial rotation and foot pronation were reduced (i.e. “more neutral”) by 2.7° (40%) and 2.4° (27%) respectively.
- During treadmill walking, peak pronation of the rearfoot and arch were significantly reduced, by 3.1° (23%) and 1.7° (11%) respectively. Ranges of motion were reduced by 2.7° (11%) and 2.4 (15%) respectively. Internal tibial rotation was reduced by an average of 9.2° (20%).

Alignment Outcomes Schematic

For illustration purposes, the arrows exaggerate the amount of motion observed



Neutral
Foot held with the subtalar joint in the reference, neutral position

Relaxed Stance
In relaxed stance, the foot pronates under the half bodyweight load.

Insole
Across subjects, the Align insole significantly reduced the deviation from neutral, but the EVA insole did not.

Figure 3

Insole Physical Properties

Weight and Thickness [4]

Compared with a sample of 20 competitive after-market insoles, the Align product is in the mid-range of thicknesses in both heel (8.9 mm) and forefoot (6.1 mm). At 1.6 ounces per insole[5], the Align was the lightest of the sample insoles[6].

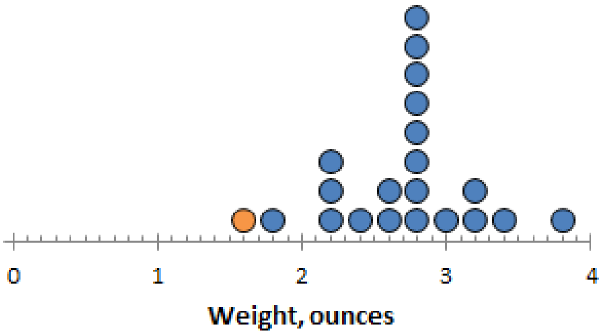


Figure 4: Distribution of weights of Align insole (●) and 20 competitive after-market insoles (●)

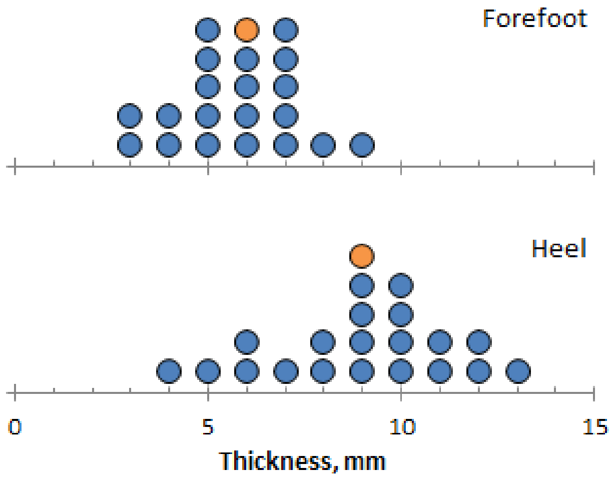


Figure 5: Distribution of heel and forefoot thicknesses of Align insole (●) and 20 competitive after-market insoles (●)

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[4] Additional results are provided in Appendix 4

[5] Men's size 10½ .

[6] The reference EVA insole weighed 0.5 ounces.

Flexibility [7]

Forefoot flexibility was determined using a test device that is commonly used for this purpose in the footwear industry. The shoe is repeatedly flexed by the device while the angle of flex and the torque produced are measured. The main test result is “flex resistance”, the slope of the torque-angle response. Lower values of flex resistance indicate greater flexibility. In running shoes, flex resistance values average about 9 Nm range from 2 to 20 Nm.

A running shoe with a (control) EVA insole produced a flex resistance of 10.0 Nm. The same shoe with EVA insole replaced by the Align product had slightly higher resistance (10.4 Nm). The 4%increase in flex resistance (loss of flexibility) is small compared with both the range of typical values (Figure 6) and the effects of conventional after-market insoles. It is also below the threshold of difference required for consumers to perceive in the flexibility of the shoe.

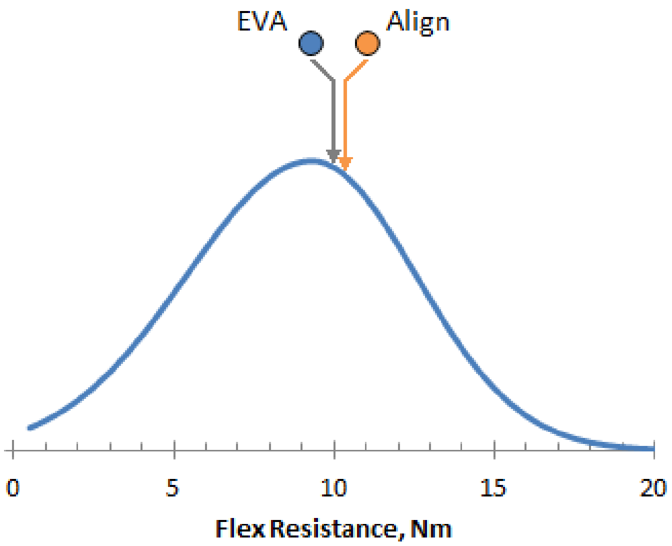
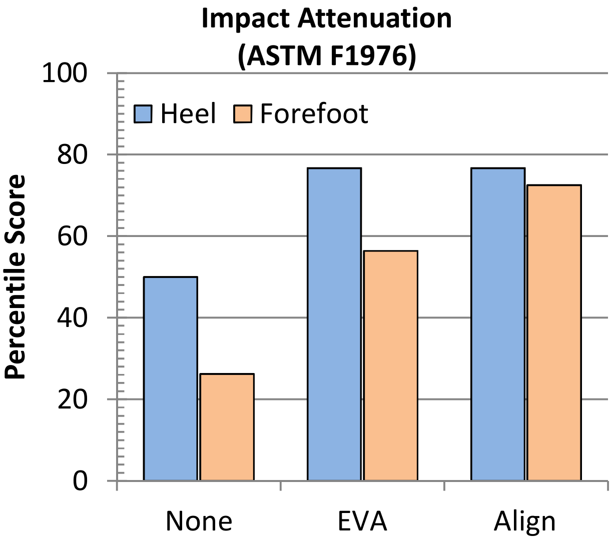


Figure 6: Distribution of forefoot flex scores found in running shoes, with current data for shoe with EVA () and Align () insoles.

Impact Attenuation [5]

Impact attenuation was compared using peak impact shock (g-max) scores from a standard impact test method[8]. The percentile scores in the chart are based on comparisons with a database of similar results from a large number of running shoes.
Both the stock EVA and Align insoles improved impact attenuation compared to the bare sole. The insole effects were similar in the heel, but the Align insole was more effective in the forefoot.



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[7] Additional results are provided in Appendix 5

[8] ASTM F1976 with 5 Joules total energy input.

Appendix 1: Human Subjects Study

Twenty subjects (8 ♂, 12 ♀) participated in a study comparing in-shoe loads and lower extremity motion during treadmill walking.

Subjects walked on a motorized treadmill at a self-selected “brisk” walking speed wearing a generic, ”neutral-cushioned” running shoe (Figure A1-1) of appropriate size for 2-3 minutes. One trial was performed with the stock EVA insole and another with Align insoles. Separate trials were conducted for pressure and motion measurements.

Alignment and Motion Capture

Lower extremity motion was recorded in three dimensions using a Natural Point motion capture system with 12 cameras running at 100 frames per second. Reflective marker triads mounted on lightweight stiff antennae were used to define rigid bodies and track the motion of the lower leg, foot and shoe (Figures A1-1 and A1-2).

Baseline measurements of lower extremity alignment were made barefoot and in both shoe insole conditions; in each case (1) with the subject in relaxed stance and (b) with the subtalar joint aligned in an anatomically “neutral” orientation[9].

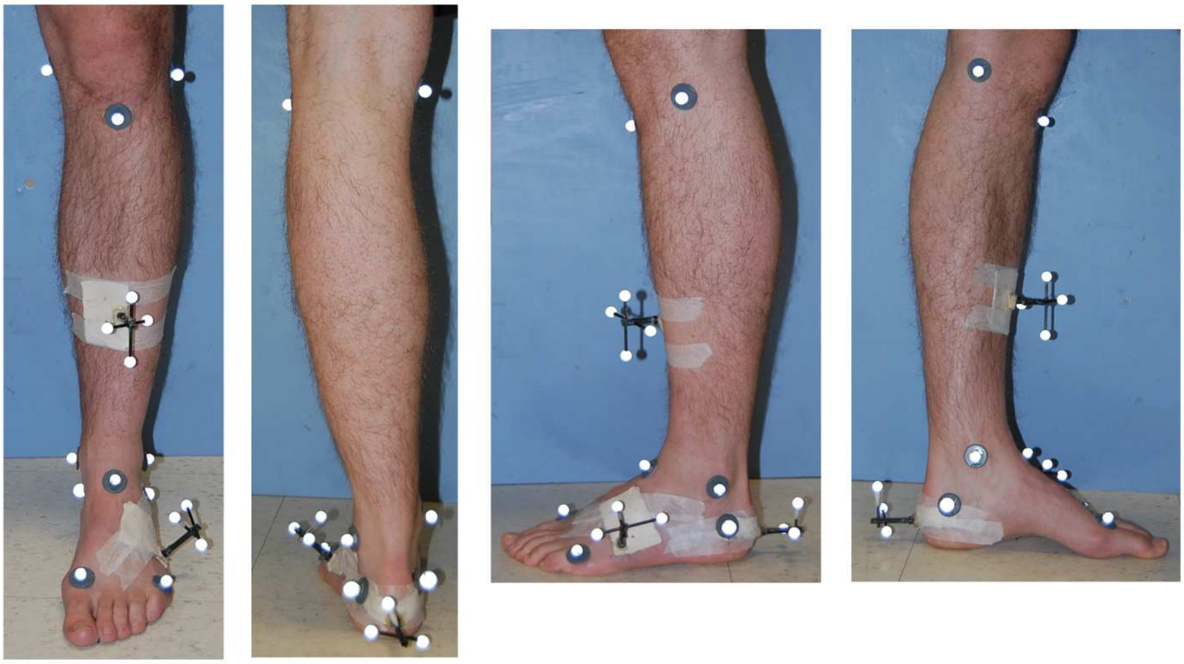

Figure A1-1: Marker set for calibration and alignment measurement

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[9] See Appendix 2

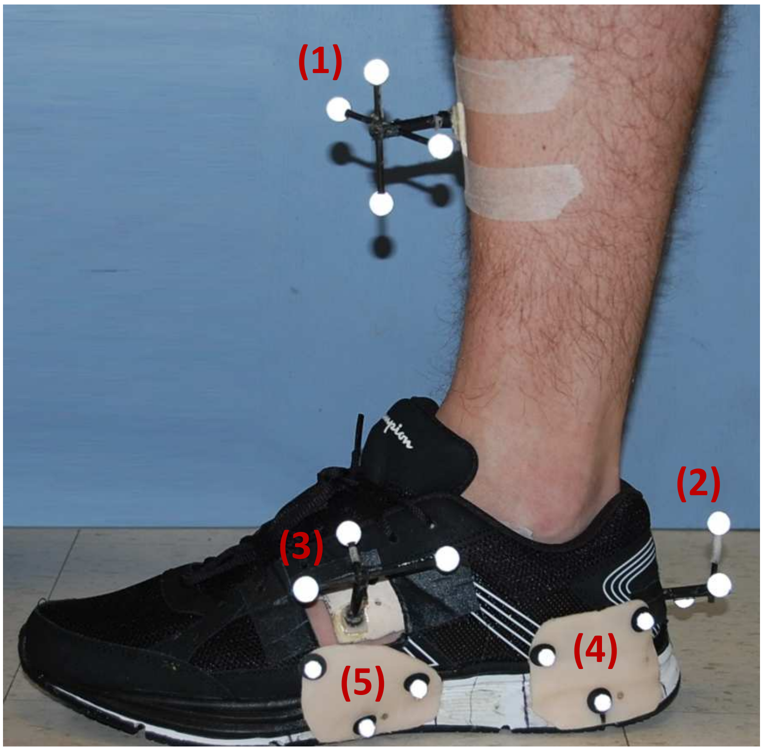


Figure A1-2. Lower leg, foot and shoe marker sets defining rigid bodies for (1) Tibia (2) foot heel segment (3) midfoot segment (4) shoe heel and (5) shoe midfoot. Note that foot antennae are mounted to custom-molded plates glued to the foot and protrude through cut-out in the shoe.

In-Shoe Pressure Measurements

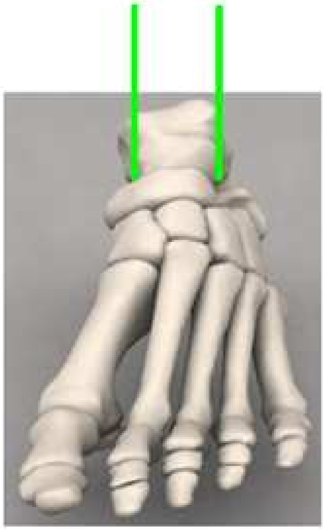
In-shoe pressure distribution was measured using F-Scan pressure sensing insoles with data transmitted wirelessly at 100 samples per second (Figure A1-4*).*

Figure A1-3: Example of generic running shoes used in all trial

Figure A1-4: F-Scan in-shoe pressure sensors

Appendix 2: Palpation of Subtalar "Neutral" Orientation

Pronated



"Neutral"

Supinated

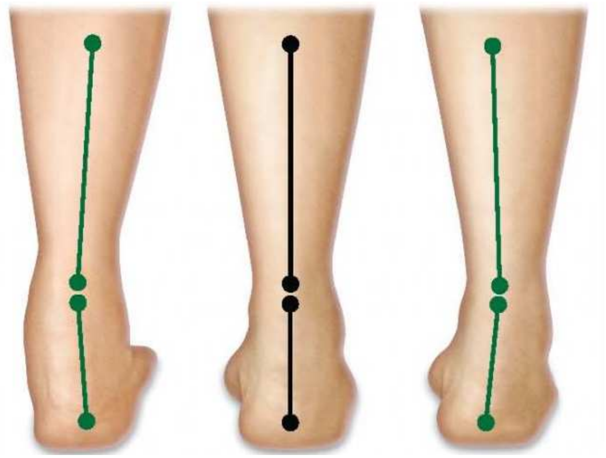
Appendix 3: The Pronation Paradigm

The "pronation paradigm" has been a dominant theme in podiatry, orthotic treatment and athletic footwear design for many years. The paradigm is based on the notion that excessive pronation of the foot is a significant factor in a number common foot and lower leg injuries.

Commonly, pronation is depicted as shown at right, in a posterior or "rearfoot" view. From this perspective, "pronation" is a rolling inward of foot ankle and "supination" is a rolling motion in the opposite direction.

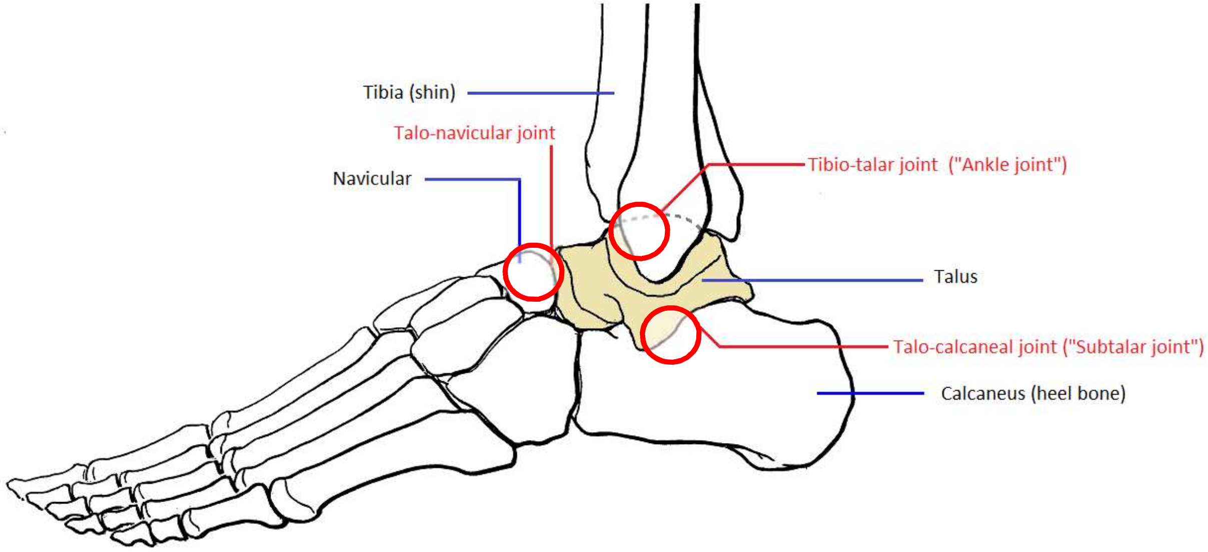
Pronation-supination is more complicated than the 2D rearfoot view suggests. It is a motion about the talo-calcaneal ("subtalar") joint that combines "rolling" of the heel with external rotation ("turning out") of the foot and dorsiflexion ("toes up" flexion).

Also, since the talus also connects to the midfoot, most importantly to the navicular bone, pronation also involves motion of the midfoot and arch. In fact, midfoot pronation and supination is commonly more significant than the heel motion component.



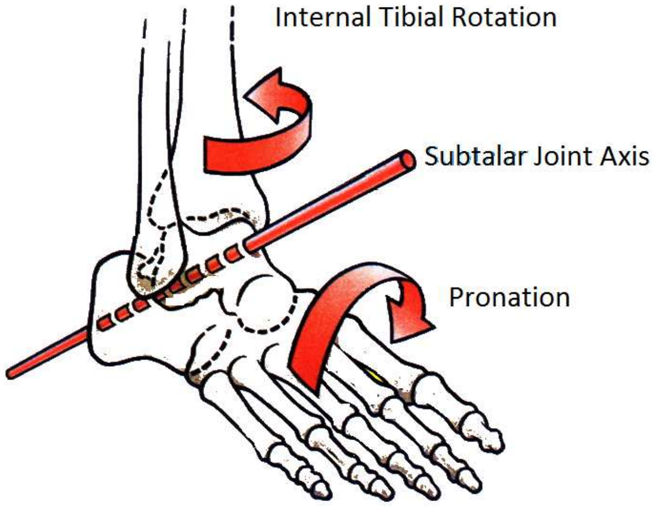
Pronated Neutral Supinated

Right Foot



The complex 3D motion occurs because the ankle is not a simple hinge joint, but a combination of joints with different orientations. The subtalar joint axis is tilted, relative to the body's axes, in all three planes. The "oblique hinge" of the subtalar joint has some important effects:

- The pronation/supination axis is not aligned with any of the major foot and leg axes.
- Pronation is accompanied by a medial shift of the ankle and midfoot ("navicular shift")
- In a fixed coordinate system pronation of the foot requires compensatory internal rotation of the tibia.



Pronation and Injury

"Excessive" pronation has been associated with overuse injuries, particularly in runners. These include "runner's knee", Achilles tendinitis, plantar fasciitis and other common injuries.

Very briefly, the pronation paradigm purports the following:

1. Flat, flexible feet pronate excessively, resulting in abnormal loading of the foot and transmission of twisting forces to the knee. Such feet require correction in the form of arch support, medial posting, etc. to resist pronation.
2. High arched feet are rigid and do not pronate enough. Pronation and flexion of the arch are themselves internal cushioning mechanisms that absorb loads on the foot. Such feet are inherently stable but require cushioning to compensate for the lack of foot flexibility.
3. Ideally, the foot should be "neutrally" aligned, i.e. neither pronated nor supinated (See Appendix 2).

It is important to note that views on the value of the pronation paradigm vary and that some elements of it have not been supported by controlled laboratory studies. Even so, the concepts of "pronation" and "pronation control" remain focal in the treatment of athletic injuries, the prescription of orthotics and the design of running shoes.

Appendix 4: Insole Weight and Thicknesses

The reference sample comprised 20 after market insoles, all full length and suitable for Men's size 10½.

Code	Weight (per insole)		Thickness,mm	
	gm	oz	HL	FF
Generic EVA				
C2	15	0.53	5.9	3.9
After-Market Insoles				
A1	77	2.73	9.2	6.4
A2	77	2.71	8.3	5.5
A3	60	2.13	4.2	2.8
A1	62	2.19	7.8	5.0
B2	78	2.76	6.3	3.6
D1	65	2.3	11.3	7.7
D2	88	3.1	12.7	7.3
E1	50	1.77	8.9	6.2
E2	77	2.72	11.8	8.7
E3	73	2.58	4.8	4.6
E4	106	3.75	6.3	3.5
E6	77	2.72	9.7	6.3
E7	76	2.68	9.3	6.4
E8	77	2.70	9.0	6.8
E9	72	2.55	10.2	5.4
E10	75	2.63	10.1	5.5
E11	60	2.11	7.2	4.4
E12	88	3.10	10.1	6.8
E13	96	3.38	11.0	6.9
E14	80	2.83	12.4	7.2
Average	75.7	2.6	8.9	5.9
Standard Deviation	12.8	0.5	2.4	1.5
Minimum	50.3	1.8	4.2	2.8
Maximum	106.3	3.7	12.7	8.7
Align Insole				
	46.1	1.62	8.9	6.1

Appendix 5: Mechanical Test Results

The table below shows the results of mechanical flexibility and impact tests

			Insole		
			None	**EVA**	**Align**
Thickness	Heel	mm	27.9	31.7	40.5
	Forefoot	mm	17.7	21.3	27.4
Flex Resistance	k1	Nm		10.00	10.40
Heel Impact	g-max	g	11.9	11.0	11.0
	g-max	%ile	50	77	77
	x-max	mm	9.9	12.3	13.1
	Eret	%	52	54	54
Forefoot Impact	g-max	g	17.8	15.2	14.4
	g-max	%ile	26	56	73
	x-max	mm	9.2	10.4	12.5
	Eret	%	44	55	50

KEY:

Item	Units	Description
Thickness	mm	Heel and forefoot thicknesses measured at 12% and 75% of insole length from the heel, respectively.
Flex Resistance	Nm	The slope of the relationship between the torque resisting forefoot flex and the angle of flex; measured between 10° and 40° of flexion. Higher values indicate greater resistance to flex, i.e. less flexibility.
g-max	g	Peak impact shock recorded on a standard impact test and expressed as acceleration in gravitational (g) units. Higher values indicate greater peak impact shock, i.e. less impact attenuation.
g-max	%ile	Expresses the g-max score of an impact test as a percentile of the distribution of scores found in a large sample of running shoes. A percentile score of ***X*** indicates that the impact attenuation (cushioning) of the shoe is at least as good as or better than X% of shoes in the market place.
x-max	mm	Peak compression of the sole during impact test. Higher values indicate greater compressibility.
Eret	%	The portion of impact energy that is returned during recovery (“rebound”) higher values indicate a more resilient or more ”springy” sole.